Section 5.0

510(k) Summary

APR 16 2007

Submitter Name:	ISTO Technologies, Inc.
Submitter Address:	1155 Olivette Executive Parkway, Suite 200 St. Louis, Missouri 63132
Contact Person:	Gary Gage Program Director
Phone Number: Fax Number:	314-995-6049 314-995-6025
Date Prepared:	November 3, 2006
Device Trade Name:	InQu™
Device Common Name:	Resorbable bone void filler
Classification Name: Classification Number: Product Code:	Filler, bone void, calcium salt compound 21 CFR 888.3045 MQV
Predicate Devices:	PolyGraft™ BGS, OsteoBiologics, Inc., K040047
Statement of Intended Use:	InQu™ is a resorbable bone void filler intended to fill bony gaps or voids that are not intrinsic to the stability of the bony structure. InQu™ is intended to be gently packed into bony gaps or voids in the skeletal system (extremities and pelvis). These defects may be surgically created or result from traumatic injury to the bone.
Device Description, Summary of Technological Characteristics, and Comparison to the Predicate Device	InQu™ is intended for single patient use only. InQu™ is a sterile, granular, synthetic bone void filler device composed of poly (D, L-lactide-co-glycolide) and hyaluronic acid. It resorbs and is replaced with bone during the healing process. Testing has confirmed InQu™ is biocompatible as a bone void filler device. InQu™ is substantially equivalent to the predicate device in terms of material composition, technological characteristics and bone healing performance in an animal model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ISTO Technologies
c/o Ms. Patsy J. Trisler, J.D., RAC
5600 Wisconsin Ave.
#509
Chevy Chase, MD 20815

APR 16 2007

Re: K063359
Trade Name: InQu™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: January 29 2007
Received: January 30, 2007

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson

Mark N. Melkerson.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063359

Device Name: InQu™

Indications for Use:

InQu™ is a resorbable bone void filler intended to fill bony gaps or voids that are not intrinsic to the stability of the bony structure. InQu™ is intended to be gently packed into bony gaps or voids in the skeletal system (extremities and pelvis). These defects may be surgically created or result from traumatic injury to the bone.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Barbara Brenner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063359